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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/892,485	Applicant(s) ISHIHARA ET AL.	
	Examiner Arun Chakrabarti	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-10 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Election/restriction

1. Applicant's election of Group I, corresponding to claims 1-10, and 15-20, is hereby acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10, and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 10 are rejected as indefinite because the instantly claimed methods lacks final process steps that clearly relates back to the preamble. For the method of claim 1-4 and 10, the preamble of the instantly claimed methods are drawn to a method for detecting an endocrine disrupting action of a test substance while the final process step is that of detecting a gene specific to the first gene expression pattern and it is thus unclear as to whether the instantly claimed method is drawn to a process for detecting an endocrine disrupting action of a test substance or rather detecting a gene specific to the first gene expression pattern. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the

method which were stated in the method's preamble. Claims 1-4 and 10 lack such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claims 15-17 are rejected as indefinite because the instantly claimed methods lacks final process steps that clearly relates back to the preamble. For the method of claims 15-17, the preamble of the instantly claimed methods are drawn to a method for detecting an endocrine disrupting action of a test substance while the final process step is that of detecting a glycoprotein specific to the first glycoprotein pattern and it is thus unclear as to whether the instantly claimed method is drawn to a process for detecting an endocrine disrupting action of a test substance or rather detecting a glycoprotein specific to the first glycoprotein pattern. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claim 1 lacks such a last step and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Regarding claim 20, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-4 are rejected under 35 U.S.C. 102 (e) as being anticipated by Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999).

Lonial et al teach a method of detecting an endocrine disrupting action of a test substance (Abstract), comprising:

a) culturing a cell having a sensitivity to an endocrine hormone in a first culture system in which endocrine hormone and the test substance are present (Claim 12 and column 10, line 65 to column 12, line 16);

b) determining the presence or absence of an endocrine disrupting action of the test substance by comparing a first gene expression pattern obtained from the cell of the first culture system with a second gene expression pattern expressed by a cell having a sensitivity to the endocrine hormone (Claim 12 and column 10, line 65 to column 12, line 16 and Figure 3).

Lonial et al inherently teach a method comprising a second, third and fourth culture system in which presence and absence of endocrine hormone and test substances are modulated (Claim 12 and column 10, line 65 to column 12, line 16 and Figure 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 7, 9, and 15-17 are rejected under 35 U.S.C. 103 (a) over Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999) in view of Gillies et al. (U.S. Patent 4,663,281) (May 5, 1987).

Lonial et al teach a method of claims 1-4 as described above.

Lonial et al do not teach a method, wherein comparison of the gene expression patterns are made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation.

Gillies et al teach a method, wherein comparison of the gene expression patterns are made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation (Figures 2, 7, and 8).

Lonial et al do not teach a method, wherein comparison of the gene expression patterns are made by hybridizing gene groups, and subtracting unhybridized genes.

Gillies et al teach a method, wherein comparison of the gene expression patterns are made by hybridizing gene groups, and subtracting unhybridized genes (Figures 7-8).

Lonial et al do not teach a method, wherein glycoprotein is expressed in cells.

Gillies et al teach a method, wherein glycoprotein is expressed in cells (Column 5, lines 30-37).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein glycoprotein is expressed in cells and wherein comparison of the gene expression patterns are made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation of Gillies et al in the method of Lonial et al, since Gillies et al states, "More specifically, the invention relates to a method of exploiting the genetic mechanism of certain types of eukaryotic cells to produce relatively large quantities of a protein of interest or its

precursor (Column 1, lines 11-15)" Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein glycoprotein is expressed in cells and wherein comparison of the gene expression patterns are made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation of Gillies et al in the method of Lonial et al. in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Gillies et al, of an invention which relates to a method of exploiting the genetic mechanism of certain types of eukaryotic cells to produce relatively large quantities of a protein of interest or its precursor and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

8. Claims 1-4, 8 and 10 are rejected under 35 U.S.C. 103 (a) over Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999) in view of Pearson et al. (U.S. Patent 5,916,779) (June 29, 1999).

Lonial et al teach a method of claims 1-4 as described above.

Lonial et al do not teach a method, wherein RNA is recovered and subjected to RT PCR to detect a band specific to gene expression pattern.

Pearson et al teach a method, wherein RNA is recovered and subjected to RT PCR to detect a band specific to gene expression pattern (Abstract, Claim 1 and Figure 1 and Column 2, lines 13-56).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein RNA is recovered and subjected to RT PCR to detect a band specific to gene expression pattern of Pearson et al in the method of Lonial et al, since Pearson et al states, "Amplification of RNA and DNA targets is often desirable for diagnostic application of amplification technologies, as this gives the greatest number of amplifiable targets per sample. , and as a result, the greatest diagnostic sensitivity. Amplification of RNA targets is also useful for diagnostic monitoring of RNA-related conditions such as certain viremias, up regulation of cancer genes, etc. Amplification of RNA targets is referred to as "reverse transcription amplification", the best known method being reverse transcription PCR.(Column 2, lines 17-26)". Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein RNA is recovered and subjected to RT PCR to detect a band specific to gene expression pattern of Pearson et al in the method of Lonial et al. in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Pearson et al, of an invention which provides

amplification of RNA targets by the best known method reverse transcription PCR useful for diagnostic monitoring of RNA-related conditions such as certain viremias, up regulation of cancer genes, etc. and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

9. Claims 1-6 are rejected under 35 U.S.C. 103 (a) over Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999) in view of Comoglio et al. (U.S. Patent 6,030,949) (February 29, 2000) further in view of Cubicciotti (U.S. Patent 6,287,765 B1) (September 11, 2001).

Lonial et al teach a method of claims 1-4 as described above.

Lonial et al do not teach a method, wherein cell is Neuro2a.

Comoglio et al. teach a method, wherein cell is Neuro2a (Examples 2 and 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein cell is Neuro2a of Comoglio et al in the method of Lonial et al, since Comoglio et al states, "The invention refers to transduced cells for use in the therapy of the above mentioned pathologies (Column 2, lines 6-8)". Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein glycoprotein is expressed in cells and wherein comparison of the gene expression patterns are

made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation of Gillies et al in the method of Lonial et al. in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Comoglio et al, of an invention which refers to transduced cells for use in the therapy of certain neurodegenerative pathologies and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

Lonial et al. in view of Comoglio et al do not teach a method, wherein endocrine hormone is triiodothyronine.

Cubicciotti teaches a method, wherein endocrine hormone is triiodothyronine (Column 182, lines 18-46).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein endocrine hormone is triiodothyronine of Cubicciotti in the method of Lonial et al. in view of Comoglio et al., since Cubicciotti states, "Examples of analytes for which such a complex is useful include, but are not limited to, hormones such as thyroxine and triiodothyronine (Column 182, lines 28-30)". Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary

practitioner would have been motivated to combine and substitute the method wherein endocrine hormone is triiodothyronine of Cubicciotti in the method of Lonial et al. in view of Comoglio et al. in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Cubicciotti, of triiodothyronine which refers to examples of equivalent useful analyte complex and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

10. Claims 1-7, 9 and 15-19 are rejected under 35 U.S.C. 103 (a) over Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999) in view of Gillies et al. (U.S. Patent 4,663,281) (May 5, 1987) further in view of Comoglio et al. (U.S. Patent 6,030,949) (February 29, 2000) further in view of Cubicciotti (U.S. Patent 6,287,765 B1) (September 11, 2001)..

Lonial et al. in view of Gillies et al teach the method of claims 1-4, 7, 9, and 15-17 as described above.

Lonial et al. in view of Gillies et al do not teach a method, wherein cell is Neuro2a.

Comoglio et al. teach a method, wherein cell is Neuro2a (Examples 2 and 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein cell is Neuro2a of Comoglio et al in the method of Lonial et al in view of Gillies et al, since Comoglio et al states, "The invention refers to transduced cells for use in the therapy of the above mentioned pathologies (Column 2, lines 6-8)". Moreover, Lonial et al provide further motivation as Lonial

et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein glycoprotein is expressed in cells and wherein comparison of the gene expression patterns are made by comparing bands obtained by subjecting a gene group contained in each of gene expression patterns to electrophoretic separation of Gillies et al in the method of Lonial et al. in view of Gillies et al in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Comoglio et al, of an invention which refers to transduced cells for use in the therapy of certain neurodegenerative pathologies and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

Lonial et al. in view of Gillies et al. further in view of Comoglio et al. do not teach a method, wherein endocrine hormone is triiodothyronine.

Cubicciotti teaches a method, wherein endocrine hormone is triiodothyronine (Column 182, lines 18-46).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein endocrine hormone is triiodothyronine of Cubicciotti in the method of Lonial et al. in view of Gillies et al. further in view of Comoglio et al., since Cubicciotti states, "Examples of analytes for which such a

complex is useful include, but are not limited to, hormones such as thyroxine and triiodothyronine (Column 182, lines 28-30)". Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein endocrine hormone is triiodothyronine of Cubicciotti in the method of Lonial et al. in view of Gillies et al. further in view of Comoglio et al., in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Cubicciotti, of triiodothyronine which refers to examples of equivalent useful analyte complex and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

11. Claims 1-4, 7, 9, 15-17, and 20 are rejected under 35 U.S.C. 103 (a) over Lonial et al. (U.S. Patent 6,001,560) (December 14, 1999) in view of Gillies et al. (U.S. Patent 4,663,281) (May 5, 1987) further in view of Makari (U.S. Patent 4,752,471).

Lonial et al. in view of Gillies et al teach the method of claims 1-4, 7, 9, and 15-17 as described above including the electrophoresis.

Lonial et al. in view of Gillies et al do not teach a method, wherein protein is recovered from the glycoprotein by cutting off the polysaccharide chain.

Makari teaches a method, wherein protein is recovered from the glycoprotein by cutting off the polysaccharide chain (Claim 5).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein protein is recovered from the glycoprotein by cutting off the polysaccharide chain. of Makari in the method of Lonial et al in view of Gillies et al., since Makari states, "The present invention relates to cancer detection preparations, their administrations and their methods of manufacture (Column 1, lines 28-30)." Moreover, Lonial et al provide further motivation as Lonial et al state, "The search for such agonists and antagonists would be facilitated by the development of a fast and effective in vitro screening system (Column 2, lines 29-31)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the method wherein protein is recovered from the glycoprotein by cutting off the polysaccharide chain. of Makari in the method of Lonial et al. in view of Gillies et al in order to improve the process for detecting an endocrine disrupting action of a test substance and in order to achieve the express advantages, as noted by Makari, of an invention which relates to cancer detection preparations, their administrations and their methods of manufacture and also in order to achieve the express advantages, as noted by Lonial et al, which would facilitate the search for hormone agonists and antagonists by the development of a fast and effective in vitro screening system.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237

Arun Chakrabarti,

Patent Examiner,

April 05, 2002

Arun kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER